EXHIBIT G

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
Master File No. 2:12-MD-02327
MDL No. 2327
JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:
Sharon Carpenter, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00554

Joy Essman, et al. v. Ethicon, Inc., et al.,
Civil Action No. 2:12-cv-00277

Barbara A. Hill, et al. v. Ethicon, Inc., et al.,
Civil Action No. 2:12-cv-00806

Brenda Riddell, et al. v. Ethicon, Inc., et al.,
Civil Action No. 2:12-cv-00547

Barbara J. Vignos-Ware, et al. v. Ethicon, Inc., et al.,
Civil Action No. 2:12-cv-00761

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RALPH ZIPPER, M.D., FACOG, FPMRS
March 20, 2016

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So at the end of the day, the overall failure rate, when you consider untreated compartment, is dramatically higher with Prolift compared to native tissue. Withagen demonstrates that. When Withagen looks in his next paper and reports on it, all compartments, not just the treated compartment failure, even use the hymenal ring, Prolift performs four times worse than native tissue.

And this is something that's been shown over and over again by other authors.

Q. Dr. Zipper, is your interpretation of that comparison that we just read, is your interpretation that, when you consider all compartment failure between the groups, that mesh fared worse?

A. Remember I said I wouldn't look at this one Withagen paper in isolation, because those authors continue to report on that -- on that data set,

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and when they went pack and report on that data set including the untreated compartment failure, they realized that the mesh performed very poorly in comparison. The Prolift performed very poorly in comparison to the native tissue surgery, secondary to the incredibly high incidence of untreated compartment failure, as over 50 percent in the anterior compartment, meaning when you treat the anterior compartment with Prolift and not the posterior compartment, Withagen found a 50 percent incidence -- 53 percent incidence of untreated compartment failure.

And when Withagen went back and looked at that, the Withagen group said, "Wow, when we look at all the compartments, this is a bust. The Prolift ends up with a much higher failure rate compared to the native tissue surgery, even when we look at the hymenal ring as the endpoint and not Stage 0 and Stage 1 prolapse."

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Q. Doctor, you have some opinions in your reports regarding the information warnings for Prolift and Prosima. And you say that those are inadequate, correct?

MR. THORNBURGH: Objection.

THE WITNESS: Yes.

BY MR. TOMASELLI:

Q. All right. And when do you believe you became an expert in warnings, sir?

A. I am -- I represent myself as an industry expert in labels and safety and -- and safety and efficacy analysis and validation. And in the last two years alone, I've been hired at the executive level to create labels, labeling guidelines, safety and efficacy plans for medical devices from companies that had been publicly traded in the past that have multi-million dollar valuations.

My expertise in industry standards, including labeling, safety and

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efficacy, is by way of 20ish years of working as an educator in the industry, educating over a thousand surgeons, educating hundreds of sales representatives, educating executives from device companies, working as a consultant for device companies, editing labels, creating -- providing labeling advice, helping bringing devices to market for those companies, working as an executive for my own device companies, creating labeling plans, creating labels, creating safety and efficacy plans.

In the last year alone, I've done that, as I've stated, for two companies. And as little as two weeks ago, I was hired as an executive to create a labeling plan and a safety and efficacy plan for another multi, multi-million-dollar valuation company coming to the market.

So based on this accumulation of experience, I've become intimately familiar with industry

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standards in safety, efficacy, and labeling.

And I take those standards when I'm going to look at a device like Prolift or Prosima, and I look at all of the medical and scientific literature pertaining to that device. I look at all the internal documents pertaining to that device. I combine that with my knowledge, training, and experience, and I put that against the standards which I am so intimately familiar with, which has become a significant portion of my life.

And by way of example, if we look at labeling, even though the standards are very well defined, they're also quite simple. If you're going to label, you be -- you provide complete disclosure. If it's an instruction for use, the user has to be able to safely and effectively use the device.

You need to provide all the material facts. You need to provide to the end user the uncertainties, the

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knowns, the unknowns, differences in opinion, avoid ambiguity.

And so if I'm going to look at a device, for instance, like Prolift and Prosima, by way of an example, I might say, well, if Ethicon knew or suspected that its device could cause pelvic floor tension myalgia or myofascial pain syndrome, or if Ethicon knew or even suspected that the implantation of its devices could take patients who had pelvic pain and create a difficult and unique scenario where pelvic pain was worsened and uniquely difficult to treat, well, if I was to find they knew that, then I would find that they didn't disclose the material facts and, therefore, their label would be outside the standards which I've come to know.

When we look at safety and efficacy, really, I -- there are two basic categories: the clinical evaluation categories and the quality

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system categories.

For the quality systems, for example, by way of example, when we look at Ethicon, they established standardized quality systems. They had a good DDSA policy. They had a good failure modes -- effects analyses policy.

But they didn't -- they weren't true to them. They didn't enforce them. They breached the wrong policies. Therefore, there's a deviation from the standard.

Safety and efficacy, very simple. Your device needs to be safe and efficacious compared to alternatives. You need to be able to demonstrate that -- lab data, animal data, human data -- and then you compare that to existing alternatives, and there's a risk/benefit analysis.

So these are the methods that I applied: my years of experience in the industry; my years of experience working as a consultant on labeling, on

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safety and efficacy; providing guidance to other people's device companies, to my own device companies; educating people from device companies.

I take those standards, worldwide standards that I've become familiar with, which I've been hired to work with and help device companies for, and I apply them to the companies based on their internal documents, based on the scientific literature, based on my knowledge, training, and experience, and either they pass the litmus test or they don't.

Q. And so if I understand your answer there, you would consider that this expertise on warnings goes back many years?

A. It's developed as a process over the course of the last 20 years.

Q. All right.

A. And I've become stronger and stronger to where, over the last couple years, I have become recognized and

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sought after by fantastic young device companies with very exciting technology at various stages of development.
Q. Right. When you say the last couple years, 2013, 2014?
A. I've been doing this for way longer than that.
Q. Okay. Fair enough.
And when do you believe -- maybe it's the same answer, but when do you believe you became an expert on what information needs to go into the IFU? Would the same answer apply?
A. It's an evolving process, but certainly I've been doing it for others for eight to ten years.
Q. Okay.
A. Doing it for myself for a little bit less than that, and over the last two years have worked more extensively as a consultant providing this type of guidance and have taken on a role as president and COO of a formerly publicly traded company with a multi --

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probably at this point a $25 million valuation to supervise their labeling, their safety and efficacy pathways, and regulatory -- I'm sorry. Not regulatory -- safety and efficacy pathways and research and development, is what I meant to say.
And just two weeks ago, another device company that exists outside the medical space has hired me for the same purposes, to help them with their labeling, to help them with their safety and efficacy, and bring them to market.
Q. You discuss some of the medical regulations for devices in your reports, and I think you just referenced them.
A. No, I actually I meant to say research and development. I corrected that.
Q. All right. In terms of the regulations pertaining to mesh and medical devices, when do you believe that

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you became an expert in those FDA regulations --
MR. THORNBURGH: Objection.
BY MR. TOMASELLI:
Q. -- that you mention in your reports?
MR. THORNBURGH: Objection.
THE WITNESS: I --
BY MR. TOMASELLI:
Q. Would it be the same answer, that it's many years?
A. My -- I represent myself as an expert in industry standards, and I gave you a narrative a moment ago describing how I developed as an expert or how I came to be intimately familiar and have expertise in the standards that pertain to labeling and safety and efficacy.
Now, those standards have been codified by the ISO, by the FDA, utilized by the Committee Européene, which is the CE that you think of.
But these are just different

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codifications of the standards which have existed forever. And if you have -- if you're familiar with the basic guidelines required to be a good, ethical human being and perform your fiduciary duties to a company, you coincidently will typically be in alignment with guidance from those various agencies, including the ISO and the FDA, and, in doing those, often be ready to have notified in body state that you meet the CE guidelines or needs, and does.
So to answer -- and in final, I've been familiar with the FDA guidelines for many years, but more crystalized to the specific codes and the minutia of it over the last few years.
Q. All right. And probably, I guess just to put a time point on that, going to the early 2010s or so?
A. I don't know.
MR. THORNBURGH: Objection.
BY MR. TOMASELLI:
Q. All right. When do you